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September 30, 2022

The Honorable Colm F. Connolly
United States District Court
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *BIAL - PORTELA & CA., S.A., et al. v. Alkem Laboratories Limited*,
C.A. Nos. 18-304-CFC-CJB, 20-786-CFC-CJB, 21-186-CFC

Dear Chief Judge Connolly:

The parties write regarding entry of final judgment in this matter. The parties have been unable to reach agreement on the form of final judgment as to the appropriate disposition of claims and patents that were not adjudicated at trial. The parties, therefore, submit competing proposals along with this letter. Exhibit A is Plaintiffs' proposal and Exhibit B is Alkem's proposal. The parties' arguments in support of their respective proposals are set forth below. The parties are available should the Court request a telephonic conference or formal briefing on this disputed issue.

Plaintiffs' position: Plaintiffs disagree that the final judgment should include a with-prejudice dismissal of counts asserting claims and patents that were not addressed at trial, in post-trial briefing, or in the Court's trial opinion. Because those claims and patents were not adjudicated by the Court, they should be dismissed as moot, but they should not be dismissed with prejudice and treated as if they had been adjudicated on their merits. This approach comports with the final judgments that Your Honor entered in *BioDelivery Sciences International, Inc. v. Alvogen PB Research & Dev. LLC*, C.A. No. 18-395-CFC-CJB (Jan. 21, 2022), D.I. 308, and *Pharmacyclics LLC v. Alvogen Pine Brook LLC*, C.A. No. 19-434-CFC-CJB (Aug. 30, 2021), D.I. 357. Here, as in *BioDelivery Sciences*, Plaintiffs included the unadjudicated claims and patents in the pre-trial order but did not present them at trial because of the need to reduce the number of asserted claims to be tried, as directed by the Court for reasons related to case management.¹ See May 13, 2022 Oral Order, C.A. No. 18-304-CFC-CJB. As in *BioDelivery Sciences* and *Pharmacyclics*, Plaintiffs believe the appropriate disposition of the unadjudicated claims is that they be dismissed as moot.

Alkem argues that two orders by Judge Andrews support dismissing with prejudice the counts involving the unadjudicated claims and patents, but those cases are distinguishable. See *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, C.A. No. 15-152-RGA (July 9, 2019), D.I. 561; *Shure Inc. v. ClearOne, Inc.*, C.A. No. 19-1343-RGA (May 22, 2022), D.I. 698. In both cases, the Court exercised discretion to dismiss *with prejudice* as to claims that the plaintiff voluntarily dropped, "[p]resumably . . . because they adjudged them to be least important to their case." *Bio-Rad Labs.*, D.I. 561 at 2. The Court in *Bio-Rad Laboratories* acknowledged that other Delaware cases had

¹ The reduction of claims in *BioDelivery Sciences* did not involve dropping any patents.

The Honorable Colm F. Connolly
September 30, 2022
Page 2

instead dismissed *without prejudice* as to claims not addressed at trial. *See Bio-Rad Labs.* at 3 n.2 (citing *Idenix Pharms. LLC v. Gilead Scis., Inc.*, C.A. No. 14-846-LPS, 2018 WL 1313973, at *1 (D. Del. Mar. 14, 2018)). Here, as in *Idenix*, even the claim streamlining the parties agreed on leading up to the pre-trial order did not include any agreement that such claims or patents would be dismissed with prejudice. Plaintiffs thus respectfully request that the Court dismiss the counts involving unadjudicated claims as moot or, in the alternative, without prejudice.

Defendant's position: Counts I through V of Plaintiffs' complaint filed in C.A. No. 18-304-CFC-CJB, alleging infringement of five U.S. Patents that Plaintiffs later dropped from the case just weeks before trial, should be dismissed with prejudice. Plaintiffs filed that Complaint on February 22, 2018, and continued to assert dozens of claims from those five patents against Alkem until April 15, 2022 (for the '135 and '244 patents) or May 19, 2022 (for the '431, '929, and '747 patents). The parties litigated the infringement and validity of all five patents for more than four years—through claim construction, fact discovery, and expert discovery. Plaintiffs should not be allowed to assert those same patents against the same Alkem product in a new lawsuit in the future. *See, e.g., Shure Inc. et al. v. ClearOne, Inc.*, No. 19-1343-RGA, D.I. 698 (May 27, 2022); *Bio-Rad Labs., Inc., et al. v. 10x Genomics, Inc.*, No. 15-cv-152-RGA, D.I. 561 (July 9, 2019) (exercising discretion under Rule 15 and dismissing with prejudice Counts alleging infringement of patents that Plaintiffs dropped from suit mere weeks before trial).

Plaintiffs agree that two final judgments entered by this Court in other matters support dismissal of Counts I-V of Plaintiffs' Complaint as moot or without prejudice. *See BioDelivery Sciences International, Inc. v. Alvogen PB Research & Dev. LLC*, C.A. No. 18-1395-CFC-CJB (Jan. 21, 2022), D.I. 308; *Pharmacyclics LLC v. Alvogen Pine Brook LLC*, C.A. No. 19-434-CFC-CJB (Aug. 30, 2021), D.I. 357. Based on our review of the docket of those cases, however, it appears that the parties did not dispute the nature of the dismissal. On the other hand, when there was such a dispute in *Shure* and *Bio-Rad*, Judge Andrews dismissed the counts with prejudice because it was not “in the interests of justice to permit claims to be dropped on the eve of trial with no consequence.” *Bio-Rad* at 3. To be sure, the final determination is left to the Court's discretion. *See Bio-Rad* at 3, n. 2. In this case, the parties litigated the five patents for more than four years before the Plaintiffs dropped them—voluntarily—asserting what they felt to be their strongest patents, and it is not in the interests of justice to subject Alkem to the risk of relitigating the dropped patents again in the future.

Respectfully,

/s/ Steven J. Balick

Steven J. Balick (#2114)

SJB/nml

Attachments

cc: All counsel of record (via electronic mail; w/attachments)